REMARKS

The first paragraph of page 1 has been amended to update the status of the priority applications and to reflect recent USPTO guidance related to the formatting of priority claims in the specification. Claims 1 and 14 are herein canceled without prejudice or disclaimer. Applicants reserve the right to pursue the subject matter of the canceled claims in a related application. Claims 11, 13, 15, 17-20, 22, and 24 have been withdrawn from consideration by the Examiner. Claims 18, 34-36, and 38-43 have been amended. Claim 18 has been amended to be dependent on claim 25, such that, if claim 25 is allowed, claim 18 will be rejoined to an allowed product claim. These amendments are fully supported by the specification and original claims and do not introduce any new matter. More particularly, support for amended claims 40-43 is found in the specification, for example, at page 103, line 13. Claims 11, 13, 15, 17-20, 22, 24, and 25-51 will be pending upon entry of the present amendments.

I. Objection to Claims 14, 34-36, 38-39 under 37 CFR 1.75(c)

Claims 14, 34-36, 38-39 have been objected to under 37 C.F.R. § 1.75(c) as allegedly being of improper dependent form for failing to further limit the subject matter of a previous claim. More specifically, the Examiner states, "As regards Claim 14, please note that Claim 11 has been withdrawn as it is directed toward a non-elected invention. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form....As regards Claims 34-35, 38-39, using the claim form like that form used in Claims 30-32 would overcome these objections." *See* item 3 bridging pages 2 and 3, Paper No. 010604.

As an initial matter, Applicants note that claim 14 has been canceled, thereby rendering the rejection moot with respect to this claim. With regard to the Examiner's objection to claims 34-36 and 38-39, Applicants respectfully disagree. Applicants submit that the language of claims 34-36 and 38-39 clearly limits their scope with respect to the claim from which they depend. Nevertheless, Applicants have amended claims 34-36 and 38-39 to put them in a form consistent with claims 30-32 as suggested by the Examiner.

II. Rejection of Claims 1, 25-33, 37, and 40-51 under 35 U.S.C. §§ 101 and 112, first paragraph

Claims 1, 25-33, 37, and 40-51 have been rejected under 35 U.S.C. § 101. *See* page 3, items 4 and 5 of Paper No. 010604. More particularly, the Examiner states, "Claim(s) 1, 25-33, 37, 40-51...not supported by either a specific or substantial asserted utility or a well established utility." Applicants respectfully disagree and traverse.

As an initial matter, Applicants note that claim 1 has been canceled without prejudice or disclaimer, thereby rendering rejection of this claim under 35 U.S.C. § 101 moot. Furthermore, Applicants note that, contrary to the examination guidelines for the utility requirement as stated in MPEP §2107(II) at 2100-30, the Examiner has not set forth any reasons for the rejection under 35 U.S.C. §101. Specifically, the utility examination guidelines mandate that,

> (C) Any rejection based on lack of utility should include a detailed explanation why the claimed invention has no specific and substantial credible utility. Whenever possible, the examiner should provide documentary evidence regardless of publication date (e.g., scientific or technical journals, excerpts from treatises or books, or U.S. or foreign patents) to support the factual basis for the *prima facie* showing of no specific and substantial credible utility. If documentary evidence is not available, the examiner should specifically explain the scientific basis for his or her factual conclusions.
>
> (1) Where the asserted utility is not specific or substantial, a *prima facie* showing must establish that it is more likely than not that a person of ordinary skill in the art would not consider that any utility asserted by the applicant would be specific and substantial. The *prima facie* showing must contain the following elements:
>
> (i) An explanation that clearly sets forth the reasoning used in concluding that the asserted utility for the claimed invention is not both specific and substantial nor well-established;
> (ii) Support for factual findings relied upon in reaching this conclusion; and
> (iii) An evaluation of all relevant evidence of record, including utilities taught in the closest prior art.

Therefore, Applicants respectfully submit that the Examiner has not made a *prima facie* case for rejecting the claims under 35 U.S.C. §101 and respectfully request clarification of the rejection in the next Office Action.

Nevertheless, Applicants submit that for the reasons set forth below, the utility for the invention set forth in the specification is specific and substantial. The specification describes how the polypeptides of the invention are primarily expressed in a variety of tissues and cell types including pulmonary, endothelial, umbilical cord, and fetal tissues. *See* page 68, lines 25-26 of the present specification. The specification further states that the polypeptides of the invention may be useful, for example, in the diagnosis and/or treatment of disease and conditions, including, but not limited to, "...asthma, pulmonary edema, atherosclerosis, restenosis, stroke, thrombosis and hypertension." *See* page 68, lines 30-31 of the present specification. Applicants contend that one of skill in the art would find these asserted utilities to be specific. In addition, since the diagnosis and/or treatment of such specific diseases is certainly a "real-world" use, Applicants contend that the skilled artisan would also find the assertion of utility to be substantial. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 101.

The Examiner has further rejected claims 1, 25-33, 37, and 40-51 under 35 U.S.C. § 112, first paragraph, on page 3, item 7 of Paper No. 010604. As an initial matter, Applicants note that claim 1 has been canceled without prejudice or disclaimer, thereby rendering the rejection moot with respect to claim 1. As discussed above in response to the rejection of claims 25-33, 37, and 40-51 under 35 U.S.C. § 101, the claimed invention is supported by a specific and substantial asserted utility. The Examiner "should not impose a 35 U.S.C. § 112, first paragraph, rejection grounded on a 'lack of utility' basis unless a 35 U.S.C. §101 rejection is proper." M.P.E.P. § 2107 (IV) at 2100-36. Therefore, because the claimed invention complies with the utility requirement of 35 U.S.C. § 101, the rejection under 35 U.S.C. § 112, first paragraph, based on the alleged lack of utility of the claimed invention, cannot be maintained. Accordingly, Applicants respectfully request that the rejection of claims 25-33, 37, and 40-51 under 35 U.S.C. § 112, first paragraph, be withdrawn.

III. Rejection of Claims 1, 33, and 37 under 35 U.S.C. § 102(b)

Claims 1, 33, and 37 have been rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Sommer et al. (1989). *See* page 4, item 9 of paper No. 010604.

A. Rejection of claim 1 under 35 U.S.C. § 102(b)

Claim 1 has been canceled without prejudice or disclaimer, therefore, rejection under 35 U.S.C. § 102(b) is obviated.

B. Rejection of claims 33 and 37 under 35 U.S.C. § 102(b)

The Examiner has rejected claim 33 in view of Sommer et al. for the following reason:

> Sommer et al. teach an isolated nucleic acid molecule...comprising a first polynucleotide (i.e. 5' - GCTA - 3') 95% or more identical to a second polynucleotide selected from a defined group which includes a polynucleotide encoding amino acid residues 1-88 of SEQ ID NO: 83 or a polynucleotide encoding amino acid residues 2-88 of SEQ ID NO: 83 or a polynucleotide encoding amino acid residues 22-88 of SEQ ID NO: 83. Note, for example, that the sequence 5' - GCTA- 3' in the primer taught by Sommer is 100% identical (i.e. 95% or more) to nucleotides 909-912 of SEQ ID NO: 38 (i.e. a second polynucleotide encoding amino acid residues 1-88 of SEQ ID NO: 83 or a second polynucleotide encoding amino acid residues 2-88 of SEQ ID NO: 83 or a second polynucleotide encoding amino acid residues 22-88 of SEQ ID NO:83.

Page 6, third full paragraph of Paper No. 010604. Applicants respectfully disagree and traverse.

Applicants respectfully submit that a *prima facie* case of anticipation has not been properly made under 35 U.S.C. §102(b). The MPEP clearly states that, "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *See*, MPEP §2131 at 2100-69 *quoting Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)(emphasis added). "The identical invention must be shown in as complete detail as is contained in the ... claim." *See*, MPEP §2131 at 2100-69 *quoting Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989)(emphasis added). Applicants respectfully submit that Sommer et. al. does

not teach each and every recited element of claim 33 such that the identical invention is shown in as complete detail as is contained in the claim, as required by 35 U.S.C. §102.

The meaning of the preamble of claim 33, "...drawn to an isolated nucleic acid molecule comprising a first polynucleotide 95% or more identical to a second polynucleotide selected from a defined group which includes ..." is made clear by the following passage from Applicant's specification:

> By a polynucleotide having a nucleotide sequence at least, for example, 95% "identical" to a reference nucleotide sequence of the present invention, it is intended that the nucleotide sequence of the polynucleotide is identical to the reference sequence except that the polynucleotide sequence may include up to five point mutations per each 100 nucleotides of the reference nucleotide sequence encoding the polypeptide. In other words, to obtain a polynucleotide having a nucleotide sequence at least 95% identical to a reference nucleotide sequence, up to 5% of the nucleotides in the reference sequence may be deleted or substituted with another nucleotide, or a number of nucleotides up to 5% of the total nucleotides in the reference sequence may be inserted into the reference sequence.

Page 95, line 32 to page 96, line 11 of the instant specification.

According to the description of "95% identical" as defined by the present specification, the fragment of Sommer et. al. (5'-GATC-3') is, at most, 2% identical to the invention of claim 33 (i.e., the 4 nucleotides of Sommer et. al. divided by the 198 nucleotides of a polynucleotide encoding amino acid residues 22 to 83 of SEQ ID NO:83 is equal to 0.020 or 2%).

Furthermore, Sommer et. al. does not teach any of the polynucleotide sequences of SEQ ID NO: 38 as recited in claim 33. Because none of the recited claim elements (e.g., a polynucleotide 95% or more identical to a polynucleotide encoding amino acid residues 1 to 88 of SEQ ID NO:83; or a polynucleotide encoding amino acid residues 2 to 88 of SEQ ID NO:83; or a polynucleotide encoding amino acid residues 22 to 88 of SEQ ID NO:83) are taught in Sommer et. al., the rejection is improper. By virtue of the reasoning given above, Applicants respectfully request that rejection of claim 33 under 35 U.S.C. § 102(b) be withdrawn.

The Examiner has rejected claim 37 in view of Sommer et al. for the following reason:

> Sommer et al. teach an isolated nucleic acid molecule (i.e. primer: 5'- TCGCAACATCGCAGCTA-3', see first primer listed Table I) comprising a first polynucleotide (i.e. 5' - GCTA - 3') 95% or more identical to a second polynucleotide encoding the amino acid sequence of the full-length polypeptide, which amino acid sequence is encoded by the HMADS4I CDNA contained in ATCC Deposit No. 209563 or a polynucleotide encoding the amino acid sequence of the secreted polypeptide, which amino acid sequence is encoded by the HMADS4I CDNA contained in ATCC Deposit No. 209563. Note, for example, that the sequence 5' ~ GCTA - 3' in the primer taught by Sommer is 100% identical to nucleotides 909-912 of SEQ ID NO: 38.

Paragraph bridging pages 6 and 7 of Paper No. 010604. Applicants respectfully disagree and traverse. By the same reasoning provided for claim 33 above, Applicants respectfully request that rejection of claim 37 under 35 U.S.C. § 102(b) be withdrawn.

C. Rejection of claims 1, 33, 37, 40-43 under 35 U.S.C. 102(e)

Claims 1, 33, 37, 40-43 have been rejected under 35 U.S.C. 102(e) as being anticipated by Jacobs et al. (US20020173635). More particularly, the Examiner states that, "Jacobs et al. teach a clone (i.e. EM42) which comprises a sequence identical to nucleotides 22-473 of SEQ ID N0:38. See the attached sequence alignment." *See* page 7, item 10, Paper No. 010604.

As a preliminary matter, Applicants submit that claim 1 has been canceled without prejudice or disclaimer, thereby obviating the rejection under 35 U.S.C. 102(e).

Applicants respectfully submit that a *prima facie* case of anticipation has not been properly made under 35 U.S.C. §102(b). The MPEP clearly states that, "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *See*, MPEP §2131 at 2100-69 *quoting Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)(emphasis added). "The identical invention must be shown in as complete detail as is contained in the ... claim." *See*, MPEP §2131 at 2100-69 *quoting Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920

(Fed. Cir. 1989)(emphasis added). Applicants respectfully submit that Jacobs et. al. does not teach each and every element of claims 33 and 37 such that the identical invention is shown in as complete detail as is contained in the claims, as required by 35 U.S.C. §102.

Applicants note that residues 22-473 of EM42 are identical to residues 484 to 935 of SEQ ID NO:38 as shown in the alignment attached to Paper No. 010604. However, the 100% identical overlap between the polynucleotide encoding the polypeptide of SEQ ID NO:83 and clone EM42 is restricted to the C-terminal 50 nucleotides of the polynucleotide encoding the polypeptide of SEQ ID NO:83 (*See* Exhibit A).

Therefore, with respect to the rejection of claims 33 and 37 under 35 U.S.C. § 102(e), Applicants respectfully disagree and traverse. Only the C-terminal 15 amino acid residues of SEQ ID NO:83 (corresponding to nucleotide residues 484-534 of SEQ ID NO:38 and nucleotide residues 22-71 of EM42) are encompassed by the alignment of SEQ ID NO:38 with clone EM42. Thus, according to the definition of % identity given in the instant specification (*See* the present response at part III, section B), the EM42 polynucleotide is **not at least 95% identical** to the portion of the SEQ ID NO:38 polynucleotide that encodes the polypeptide of SEQ ID NO:83 (note, nucleotide residues 267 to 534 of SEQ ID NO:38 encode the polypeptide of SEQ ID NO:83). In other words, the majority of the polynucleotide alignment with Jacobs et al. resides within the 3' non-coding region of the disclosed polynucleotide, and therefore is outside the scope of claims 33 and 37. Accordingly, Jacobs et. al. does not teach each and every element of claims 33 and 37 and, therefore, does not anticipate said claims. Thus, Applicants respectfully request that rejection of claims 33 and 37 under 35 U.S.C. § 102(e) be withdrawn.

With respect to claims 40-43, Applicants respectfully disagree. However, Applicants have amended these claims to recite isolated polynucleotides comprising at least 150 contiguous nucleotides of a polynucleotide encoding amino acid residues 1 to 88 of SEQ ID NO:83 (claims 40-41), or comprising at least 150 contiguous nucleotides of a polynucleotide encoding the full-length polypeptide of the HMADS41 cDNA contained in ATCC Deposit No. 209563. Support for this amendments can be found in the present specification at, for example, page 103, line 13. Applicants respectfully submit that Jacobs et. al. does not teach any of the species contained within the genus of amended claims 40-43, and therefore cannot properly anticipate said claims. Thus, Applicants

respectfully request that rejection of claims 40-43 under 35 U.S.C. § 102(e) be reconsidered and withdrawn.

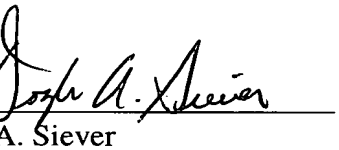
IV. CONCLUSION

Applicants respectfully request that the amendments and remarks be entered and made of record in the file history of the instant application. The Examiner is invited to call the undersigned at the phone number provided below if any further action by Applicants would expedite the examination of this application.

If there are any fees due in connection with the filing of this paper, please charge the fees to our Deposit Account No. 08-3425. If a fee is required for an extension of time under 37 C.F.R. § 1.136, such an extension is requested and the fee should also be charged to our Deposit Account.

Dated: April 12, 2004

Respectfully submitted,

By 

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